

## REMARKS

Support for the foregoing claim amendments can be found throughout the specification, and in the claims as originally filed. Specifically, support for the recitation "wherein said silencing is initiated by introduction of an exogenous nucleic acid" can be found at page 8, line 30-page 9, line 4; page 10, lines 7-11; page 11, lines 3-32; page 13, line 28-page 14, line 29; and original claims 18-30. Further, descriptions of various means of inducing gene silencing using an exogenous nucleic acid are discussed at pages 14-19. Support for the recitation "having sequence identity or similarity with the target gene" in claim 1 can be found in original claim 8. No new matter has been added.

The May 20, 2003 Official Action has been carefully reviewed. In light of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of the application are respectfully requested.

First, the Examiner maintains that a new Declaration must be submitted, because the original declaration contains a typographical error.

Next, the Examiner rejects claims 1, 5-7, 9-15, 17, 21, and 32-34 under 35 U.S.C. §112 first paragraph as allegedly lacking the full scope of enablement.

Finally, the Examiner concludes that the claims are free of the prior art.

The foregoing constitutes the entirety of the issues raised in the May 20, 2003 Official Action. In light of the present claim amendments and the following remarks, the above-noted rejection under 35 U.S.C. § 112, first paragraph is respectfully traversed.

## PRIORITY

It is the Examiner's position that the declaration is

insufficient to perfect foreign priority, due to a minor typographical error in the originally filed declaration. As set forth in the last response, Applicant's declaration is in full compliance with all of the requirements for perfecting foreign priority. Nonetheless, the Examiner has maintained his position that a new declaration must be submitted in order to perfect priority. Accordingly, applicants are in the process of obtaining a newly executed declaration, and will submit the amended declaration to the USPTO immediately upon receipt of the same. Therefore applicants request that this requirement be held in abeyance until such declaration can be prepared and submitted.

**THE CLAIMS ARE FULLY ENABLED BY THE DISCLOSURE IN THE  
SPECIFICATION**

The Examiner states that claims 1, 5-7, 9-15, 17, 21, and 32-34 are rejected under 35 U.S.C. §112, first paragraph, asserting that the specification allegedly fails to provide enablement commensurate in scope with the present claims.

Applicants respectfully submit, however, that the full scope of the claims is enabled by the present specification. As noted in the MPEP at § 2164,

The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.  
[*Emphasis supplied.*]

In § 2164.01, the MPEP continues,  
The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

(Quoting *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)).

The Examiner has maintained the rejection under 35 U.S.C. §112, first paragraph on multiple grounds. First, it is the Examiner's position that SRMs are always correlated with exogenous nucleic acid molecules. Next, the Examiner states that the claims still lack a correlation step which links identification of SRMs having sequence homology to a target gene, with silencing of that gene. The Examiner then argues that in the case of a non-exogenous gene, phenotypic change is necessary to determine the presence of gene silencing. Applicants respectfully traverse this rejection as it pertains to the present claims.

First, applicants again submit that introduction of an exogenous nucleic acid is not necessary to induce silencing. As set forth in Applicant's previous response, introduction of an exogenous nucleic acid is just one of many possible ways to initiate silencing. For example, at page 8, line 30-page 9, line 4, conventional means of gene silencing are discussed, including RNA mediated defense against viral infection, and virus resistance. Plant resistance to RNA viruses is often mediated by gene silencing which is initiated by an endogenous nucleic acid. See Example I of the instant application. Accordingly, applicants submit administration of an exogenous nucleic acid is not necessary to induce gene silencing. Nonetheless, in the interest of expediting prosecution, applicants have amended independent claims 1 and 12 to indicate that the gene silencing is initiated by an exogenous nucleic acid. Further, applicants note for the record that the new recitation "wherein...silencing is initiated by introduction of an exogenous nucleic acid" includes methods where exogenous molecules induce silencing themselves, and methods where exogenous nucleic acid molecules (such as

viruses) are introduced to the organism, and then silenced by endogenous molecules.

Second, applicants maintain the position that the SRMs by their very nature will share homology with the target gene. In order for SRMs to bind to their target gene, the skilled artisan would recognize that they must share some degree of homology. Further, the previous claim amendments make this correlation even more clear. Nonetheless, solely in the interest of expediting prosecution, applicants have amended the claims to recite this correlation.

Finally, the Examiner indicates that while the specification does correlate the presence of SRMs with introduction of known exogenous nucleic acid molecules into plants, the specification allegedly does not correlate the presence of SRMs with the silencing of any random unknown gene without a corresponding phenotypic change.

Applicants disagree, and again submit that a phenotype is not necessary to determine if gene silencing has occurred. As recited in the instant methods the skilled artisan can test a given plant for SRMs, and by sequence analysis deduce which genes are subject to silencing in that plant. There is nothing unpredictable about this - quite the opposite it is highly consistent according to all the experimental evidence, and the examiner has not challenged the evidence. Therefore the methods recited in the instant claims are enabled for detecting gene silencing, even if there is not a subsequent phenotype testing step.

Additionally SRMs may reveal the silencing of viral genes in the plant. As discussed in detail in the response filed 28 February 2003, page 8, it is possible that viral-silencing may not be considered a phenotype change or trait of the plant. In the present action (especially pages 4 and 8) the examiner has not commented on this point. Accordingly, the teachings of the specification with regard to detection of viral gene silencing (which does not necessarily produce a phenotype

change - see pages 25-26) are in direct contradiction with the Examiner's assertion that detection of phenotype change is necessary to determine gene silencing.

Finally, claims 1 and 12 (and thus claims dependent there from) now clearly recite the presence of an exogenous nucleic acid. Applicants reiterate that a phenotypic change is not necessary to determine gene silencing, because the correlation between SRM detection and gene silencing is clear.

Therefore, Applicants respectfully submit that claims 1, 5-7, 9-15, 17, 21, and 32-34 as amended fully comply with all the requirements of 35 U.S.C. §112, first paragraph, and request that the rejection of the claims under 35 U.S.C. §112, first paragraph be withdrawn.

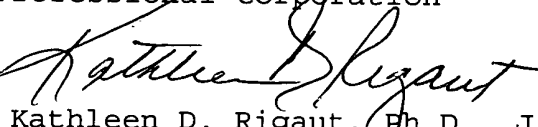
#### CONCLUSION

In view of the amendments and remarks presented herein, it is respectfully urged that the rejections set forth in the May 20, 2003 Official Action be withdrawn and that this application be passed to issue. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,

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